

REMARKS

Amendments

Claims 1-7, 20-22 and 28-34 have been cancelled without prejudice to expedite prosecution of the present application.

The use of the terms “the formation” and “the anchor” in Claim 8 has been clarified by amendment. Claim 8 has further been amended to introduce to require that the intermediate anchor molecule be immobilized on a solid phase. Antecedent basis for this amendment is located throughout the specification, particularly at page 9, lines 19-27.

Claims 11-12 and 14-18 have amended to delete the term “any of claims” that was inadvertently not amended in a previous amendment. This undersigned apologizes for this oversight.

Claims 16 and 17 have amended to delete the recitation of R^{1a} and R^{2a}, which are no longer appropriate in these claims due to amendment to remove multiple dependencies.

Claim 27 has been amended to make the claim dependent from claim 23.

New claims 35 and 36 present subject matter originally presented in claims 16 and 17.

It is respectfully submitted that these amendments are clearly minor in nature to clarify terminology, and that no new matter is introduced by these amendments.

Priority

The Examiner has indicated that certified copies of the priority documents have not been received. These documents will be filed when they are available to the undersigned.

Oath/Declaration

The Declaration as filed is stated to be defective because it does not state the city and country of each inventor. It is respectfully submitted that this statement is not correct – the city and country are stated in the declaration in the Address indication below the signature line. For example, Inventor Eichler resides in Dosenheim, Germany; inventor Frank resides in Heidelberg, Germany, and so forth. Please note that this information has been recognized on the Updated Filing Receipt mailed April 1, 2002.

Drawings

The Drawings are stated to have a number of informalities. A revised set of drawings is being filed on even date with this response. Page numbers as originally presented have been removed. Additionally, sheets previously having no figure designation have been provided with same. Thus, the entire reaction sequence as presented in Fig. 16 is now provided on a single sheet. Similarly, the various chemical structures as presented in Figure 20 are now presented as separate figures, designated Figures 20a-r. The specification has been amended to reflect this change in the drawings.

Specification

The Office Action asserts that section headings must be included, and a brief description of the drawings must be provided. No Statutory basis is provided for this asserted requirement. The MPEP provides extensive guidelines on desirable format at 608.01(a), which in turn cites 37 CFR 1.77(b). This rule provides that “the specification should include the following sections in order,” and further states that these sections “should be preceded by a section heading.” (emphasis added)

As is apparent from the language of the rule, the use of section headings in a patent application is suggested, but is not mandatory. Further, it is a widely accepted practice to not require introduction of headings in filed applications, particularly in applications that originate outside of the United States. Indeed, neither of the two granted US patent references cited in the Office Action follow the suggested format of Rule 77(b).

It is respectfully submitted that the present format of the instant patent specification is clear and understandable for examination purposes. Withdrawal of this objection in the present application is respectfully requested.

The Office Action also notes use of trademarks and comments on usage. In review of the specification, it would appear that trademark usage is proper in this application. Specifically, the terms Biacore and Sephadex are both capitalized, and additionally identified as registered marks by the ® symbol. Both of these terms are accompanied by generic terminology. It is therefore respectfully submitted that their usage is proper in the present application.

Claim Rejections – 35 USC 112

The Office Action objects to a number of claims and terms as being indefinite. These claims have by and large been amended to overcome these objections, as discussed below. Explanation regarding certain terms that are not considered to be indefinite is also provided, in the order presented in the outstanding Office Action.

Claim 8 has been rejected for being vague and indefinite for the recitation of functional language “capable of” and “enables,” with the citation of *In re Hutchison*, a 1946 case from the CCPA. It is respectfully submitted that since the time of the cited decision, the use of functional language has become accepted. MPEP 2173.05(g) states “There is nothing inherently wrong with defining some part of an invention in functional terms.” Indeed, a quick search of the claims only field of the Patent Office patent database identified 195,699 patents using the term “capable of” in the claims. It is respectfully submitted that functional language format as presented in the present claims has become accepted practice, and does not render the claim indefinite or vague.

The use of the terms “the formation” and “the anchor” in Claim 8 has additionally been objected to. The use of these terms has been clarified by amendment.

Claims 11-12 and 14-18 have been objected to because of the expression “any of claims” that was inadvertently not amended in a previous amendment. This amendment has now been carried out, with apologies for this oversight.

Claims 16 and 17 have been rejected as vague in view of recitation of R^{1a} and R^{2a}. These terms have been deleted from these claims.

Claim 18 has been rejected as being vague and indefinite for recitation of “a solid phase,” stating that it is unclear if applicant is referring to “the surface” recited in other claims or referring to a different solid phase.

It is respectfully submitted that the term “solid phase” is appropriate in this claim and clearly refers to a material different from the “surface” of other claims. The specification at page

9, lines 19-27 discuss the preparation of a ligand-anchor conjugate (“LAC”), which is made by first linking the basic units of the anchor to the solid phase used for synthesis, and then breaking this bond after successful LAC synthesis. The thus prepared LAC is then ready for immobilization on the sensing surface of the sensor by means of the anchor. In view of the clear difference of this term from “surface,” and further in view of the supported different usage of this term in the specification, it is respectfully submitted that this claim terminology is neither vague nor indefinite.

Claim Rejections – 35 USC 102

Claims 8-19 have been rejected as being anticipated by Slika et. al. (US 6,221,674 and Knoll et. al. (US 5,763,191).

The present claims provide a biosensor that comprises ligand-anchor-conjugates (“LACs”) that are provided in an exactly defined self-assembled monolayer (“SAM”) molecular structure to generate a biospecific boundary layer on the sensor surface. As noted in the present specification at page 8 beginning at line 13, the specific structure of the present LACs are carefully prepared to provide ligand-anchor conjugates whose structure is optimized for use in screening methods in form of SAMs. The LACs are a combination of an anchor molecule comprising at least one structural unit X which is capable of immobilizing the anchor on the sensor surface and an R unit which enables the formation of a self-assembled monolayer on the surface and is terminally functionalized by a group A for binding to a ligand or a non-ligand. The attachment of the ligand directly to the anchor provides a sensor that can be precisely prepared in small quantities and tailored to the specific receptor to be analyzed. In the present invention as claimed, the LAC is prepared by immobilization of an anchor molecule on a solid phase, which by definition is not the sensor surface. A ligand is then bound to the anchor molecule and the formed ligand-anchor conjugate is cleaved from the solid phase, preferably followed by formation of a self-assembled monolayer on the sensor surface.

This unique synthesis approach does not need to use large volumes of the conjugates of the affinity carrier and the anchor compounds. Further, the sensor systems utilizing the present LACs do not need large amounts of the substance to be evaluated, and do not require the use of complicated analysis steps, such as column chromatography or extraction, to carry out the substance evaluation. It is possible to carry out this synthesis because of the use of a unique

intermediate conjugate as expressly set forth in claims 8-19, which comprises an anchor molecule bound to a solid phase. The synthesis approach utilizing this unique intermediate conjugate is claimed in claims 23-27, 35 and 36. It is respectfully submitted that due to the commonality of elements in these claims, all of claims 8-19, 23-27, 35 and 36 should be examined together.

Sluka et. al. describe a process for applying spatially defined reagent areas or reagent spots on a solid phase. The reagent is applied directly to the structure of the sensor in liquid form a reagent solution. See, e.g. column 2, lines 16-39. The reagent is described generally at column 3, lines 31-38, without a teaching or suggestion of any reaction process used to form the reagent, much less the use of the unique intermediate having the anchor molecule immobilized on the solid phase as required in the claims as amended. This intermediate is not taught or suggested in the Slika process. Additionally, the present method claims requiring the reaction of this unique intermediate with a ligand to form the desired LAC, with ultimate cleavage of the LAC from the solid phase are not taught or suggested in the Slika process.

Knoll et. al. describe a method of producing a binding matrix comprising a carrier material and a solid phase reactant that is bound to the carrier material. See Column 1, lines 9-14. The solid phase reactant is adsorbed to the surface of the carrier material by anchor groups, that in turn are linked to the solid phase reactant by spacer molecules. See column 3, lines 5-6 and 20-24. The binding matrix is constructed by first preparing molecules comprising the anchor groups, spacer molecules and solid phase reactants in solution, and then adsorbing these molecules onto the carrier material. See, e.g. column 7, lines 13-25.

The claims as amended require the formation first of the unique intermediate as described above having the anchor molecule immobilized on the solid phase. This intermediate is never formed in the Knoll process, and are not taught or suggested in the Knoll disclosure. Additionally, the present method claims require the reaction of this unique intermediate with a ligand to form the desired LAC, with ultimate cleavage of the LAC from the solid phase. Thus, likewise, this process is never carried out, taught or suggested in Knoll.

Reconsideration and withdrawal of all rejections under 35 USC 102(b) is respectfully requested.

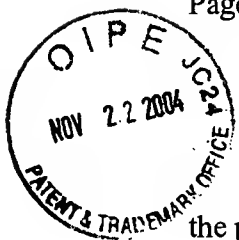
Claim Rejections – Double Patenting

All pending claims have been rejected as being unpatentable under the judicially created doctrine of obviousness-type double patenting in view of copending application 2004/0023366 A1.

It is respectfully submitted that the claims of the '366 application are not obvious in view of the present claims, and that double patenting therefore properly does not apply in this circumstance.

The '366 patent application claims relate to anchor molecules having a mercaptophilic head group suitable for covalently binding to a thiol-functionalized ligand. Specific examples of such groups are provide in the '366 application at paragraph 0014. These groups are not suggested in the present specification, as a comparison of the present general description and in particular the list of functionalities of present group A at page 13, lines 10-26 demonstrates. Advantages of the subgenus of anchor molecules as claimed in '366 are discussed in the '366 application at paragraph 0015, and include the comparatively gentle reaction conditions of the thiol/mercaptophile system as discussed and claimed, the enhanced selectivity and avoidance of inaccurate reactions with the target as a result of the fact that a thiol functionality hardly ever occurring in active substances.

Because the '366 patent application claims relate to subject matter that is not expressly disclosed in the present application, and which subject matter provides a distinct and surprising benefit as compared to the subject matter of the present claims, reconsideration and withdrawal of the outstanding rejection is earnestly solicited.



CONCLUSION

In view of the amendments and remarks provided herein, Applicants believe that all of the pending claims are in condition for allowance, and respectfully request notification thereof.

In the event that a phone conference between the Examiner and the Applicants' undersigned attorney would help resolve any remaining issues in the application, the Examiner is invited to contact the attorney at (651) 275-9811.

Dated: November 19, 2004

Respectfully Submitted,

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DRAWING AMENDMENTS

All of the drawings have been amended to remove page numbers.

Fig. 16 has been amended to provide the entire reaction sequence of the synthesis as presented on a single sheet.

Fig. 20 previously presented a large number of chemical structures, presented under a single figure designation. The various chemical structures as originally presented in Figure 20 are now presented as separate figures, designated Figures 20a-r.